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EXAMINER	
BOND, P	
ART UNIT	PAPER NUMBER
129	11

DATE MAILED: 05/10/86

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 21 MAR 1988 This action is made final.

(3)

A shortened statutory period for response to this action is set to expire THREE month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice re Patent Drawing, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449
4. Notice of informal Patent Application, Form PTO-152
5. Information on How to Effect Drawing Changes, PTO-1474
6.

Part II SUMMARY OF ACTION

1. Claims 1-11, 13-54, 57-86 and 88-101 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 1-11, 13-54, 57-71, 84-86 and 88-90 are rejected.

5. Claims 13-17, 72-83 and 91-101 are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. These drawings are acceptable;
 not acceptable (see explanation).

10. The proposed drawing correction and/or the proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been approved by the examiner. disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved. disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

(+two documents)

12. Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received

been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

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1. Claims 1-11, 13-54, 57-86 and 88-101 are now in the case.

2. It is noted with interest that applicants cite and supply a copy of Takemura et al. "29 Chem. Pharm. Bull, No. 10, pages 3019-3025 91981). The Search Examiner at the EPO cites this document as being category A; technological background. In U.S. Patent practice this is called a reference indicating the state of the art.

3. It is also noted with interest that two French Patent documents cited by the EPO Search Examiner as being category Y: particularly relevant if combined with another document of the same category. In U.S. Patent practice this would mean, in all probability, that claims 1, 3, 4, 7, 8, 14 and 18 are at least prima facie obvious within the meaning of 35 USC 103.

4. It is also noted with interest that applicants have not cited the French Patent documents on their PTO 1449 nor have they supplied a copy of either of these references. Applicants should do so if they intend to comply with the duty of disclosure and duty of disclosure.

5. Claims 1-11, 18-31, 42-54, 57-71, 84-86 and 88-90 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. It is noted that in claim 1, a term designated as R¹ has been defined but the formula does not have any term designated as R¹. There are two groups which are designated as R in the formula. It is believed that one such R group should be designated as R¹. If this is correct then correction in the formula should be made. Proper support in the original disclosure should be pointed out. If the Examiner's belief is incorrect, other appropriate changes should be made.

7. In claims 2-11, 18-31, 47-48, 51-54, and 60-71 it is noted that there is a term designated as R². Should the groups designated as R in claim 1 be designated as R¹ and R²?

8. The term "pharmaceutical" is too vague and indefinite to constitute a utility within the meaning of 35 USC 101. See, for example, *In re Kirk and Petrow*, 153 USPQ 48 (C.C.P.A. 1967) and *In re Joly and Warrant*, 153 U.S.P.Q. 45 (C.C.P.A. 1967). Thus a definite use or uses should be recited in a pharmaceutical composition or method of use claim.

9. Applicants appear to have recited definite uses in their method of use claims but not in their pharmaceutical composition claims. Both types of claims require the recitation of a definite use or uses.

10. The process of making the claimed compounds is represented by claims 18-41.

11. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

12. Claims 18-41 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen et al.

13. the process of reacting an aldehyde or ketone with 3-hydroxymethyl -3-quinuclidine to form a 2-methyl spiro (1, 3-dioxolane -4, 3') quinuclidine is entirely analogous with the process as claimed.

14. As pointed out by Cohen et al. at col. 1, lines 22-43, 3-hydroxymethyl- 3-quinuclidinol is an equivalent or alternative starting material to quinuclidine -3-epoxide. (Applicants call this compound the epoxide of 3-methylene quinuclidine).

15. Applicants (at pages 23-25 of the amendment received 21 March 1988) that the claimed processes are entirely non-analogous with those disclosed or implied by the Cohen et al. patent. These arguments are

interesting but unpersuasive since the analogy, insofar as processes are concerned, is so well established as to the fully discussed in standard texts of organic chemistry. Among these are Noller "Chemistry of Organic Compounds", Second Edition (Saunders) (1957); Royals "Advanced Organic Chemistry", (Prentice-Hall) (1954); March "Advanced Organic Chemistry", (McGraw-Hill) (1968).

16. At page 278 of Noller we note that thiols react very readily with aldehydes and ketones. At pages 203-4 of Noller we note that alcohols react with aldehydes and ketones but that the reaction is more difficult than with mercaptans.

17. At pages 627-639 of Royals we again note the analogous addition of mercaptans to aldehydes and ketones..

18. At pages 319 and 328 of Marsh we note the analogy between the reaction of epoxides with water or alcohols with reaction of epoxides with hydrogen sulfide or mercaptans.

19. At page 665 of March we note the addition of mercaptans to aldehydes and ketones. This is analogous with the addition of aldehydes and ketones as shown by March at pages 661 and 662 of March.

20. Noller at pages 744 and 745 shows that epoxides readily react with all types of compounds containing active hydrogen atoms. The products where alcohols or mercaptans are used as reactants are entirely analogous.

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21. Applicants arguments with respect to the process aspects of this application are seen as flying in the face of long established organic chemistry.

22. Claims 18-41 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen et al., taken in view of Noller, Royals and March.

23. The reasons why the textbooks are applicable as ancillary art has already been set forth above.

24. The compound, method of use and composition aspects when properly claimed, appear to be patentable subject matter. The processes for making the compounds appears to be obvious within the meaning of 35 U.S.C. 103.

25. Claims 1-11, 18-54, 57-71, 84-86 and 88-90 are rejected.

26. Claims 13-17, 72-83 and 91-101 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

27. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a).

Applicant is reminded of the extension of time policy set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD,

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THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

28. Any inquiry concerning this communication should be directed to Examiner Robert T. Bond at telephone number 703-557-3325.

5/6/88 srh



ROBERT T. BOND
PRIMARY EXAMINER
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